

DEVICE FOR THE SURGICAL TREATMENT OF FEMALE PROLAPSE**Field of the invention**

The present invention concerns a device for supporting the female pelvic organs, to be surgically implanted in uro-gynaecological treatments.

5 **State of the art**

The term "female prolapse" means the sinking or displacement through the vagina of a female pelvic organ, bladder, uterus or rectum, which may occur for only one of these organs or for more than one organ simultaneously.

In the case where the prolapse concerns the bladder, there is protrusion of the front vaginal wall, known as "cystocele", in the case where the prolapse concerns
10 the uterus, there is sinking of the upper vaginal wall, known as "hysterocele"; whereas the terms "enterocele" and "rectocele" are used when the vaginal wall affected by sinking is the rear wall and also comprises prolapse of the rectum.

When all the pelvic organs – bladder, uterus and rectum – are involved, the term
15 used is "total prolapse" and in this case the whole vagina is affected by the sinking of the internal organs, to the extent that there is often a real evagination of the vagina.

In patients who have already had a hysterectomy, and are therefore without uterus, there may be "prolapse of the vaginal vault", in which sinking principally
20 involves the bladder and the intestine.

Prolapse is a fairly frequent problem in women and may occur following a difficult vaginal birth or problems of the connective tissues.

Moreover, prolapse often appears in association with other disturbances, such as urinary or faecal incontinence. As may be easily imagined, female prolapse can
25 therefore have important affects on the quality of life and may cause severe limitations in daily living.

While there may be various approaches to treatment for incontinence, even pharmacological, depending on the diagnosis, the treatment of female prolapse is exclusively surgical.

30 Up till now, in fact, the problem of female prolapse has been solved by surgically removing the uterus. The operation provides a remedy to the contingent situation

for a short time but, as it leaves an empty space where the removed organ had been, it increases the probability of sinking of other internal organs.

A further disadvantage is that surgical operations of this type require total anaesthesia of the patient, who will also require relatively long periods of hospitalisation and convalescence.

Devices have recently appeared on the market which, when surgically implanted, allow support of the urethra and of the neck of the bladder, and are therefore useful for correcting only urinary incontinence due to stress.

Summary of the invention

The Applicant has now found a reticular or laminar device which, when surgically implanted, provides support for the female pelvic organs in the case of prolapse of the vaginal vault or partial or total prolapse through the vagina.

This device therefore makes it possible to overcome the inconvenient aspects described above concerning the prior surgical technique: the device according to the invention may in fact be vaginally, mixed vaginally/abdominally or vaginally/laparoscopically implanted, or implanted by means of mini-invasive surgery, requiring in the majority of cases only local anaesthesia, the hospitalisation and convalescence times are considerably reduced and no organ is removed.

It is therefore subject of the invention a flat implantable device made of material with a reticular or laminar structure for supporting the female pelvic organs, characterised in that it has a central body with a trapezoid shape having four arms, in which may be distinguished:

- a front portion corresponding to the smaller base of the trapezium, from the ends of which branch off in opposite directions two arms coaxial with each other and parallel to said smaller base;
- a central portion corresponding to the central part of the trapezium;
- a rear portion corresponding to the larger base of the trapezium, from the ends of which branch off two arms diverging from each other and parallel to the sides of the trapezium.

Brief description of the drawings

Figure 1: front view of the present device having a hole in the central portion and

the front portion divided into two halves by longitudinal cleft. Figures 1a and 1b differ for dimensions, respectively adapted for bigger and smaller patient body sizes.

Figure 2: front view of the present device having a hole in the central portion and the rear portion divided into two halves by longitudinal cleft. Figures 2a and 2b differ for dimensions, respectively adapted for bigger and smaller patient body sizes.

Figure 3: front view of the present device without the hole in the central portion and the longitudinal cleft. Figures 3a and 3b differ for dimensions, respectively adapted for bigger and smaller patient body sizes.

Figure 4: front view of the present device without the hole in the central portion and having the rear arms shorter than in the devices of Figures 1-3.

Detailed description of the invention

As a non limiting example of the invention:

- Figure 1a represents a front view of the device according to the invention constituted by a central body, in which may be distinguished a front portion A intended to hold the prolapsed bladder (cystocele), a rear portion D on which is placed the prolapsed intestine (enterocele), and a central portion B with the hole U which holds the uterus. The portions A, B and D into which the central body is subdivided are suitably shaped and have dimensions such as to be able to hold and support the prolapsed organs.

From the front portion A branch off the two arms E, while from the rear portion D branch off the two arms F; both pairs of arms are suitably shaped and positioned with respect to the longitudinal axis of the device in such a way that they can be anchored, during surgery, to fixed and well identified structures on the patient's pelvis.

In the device represented in Figure 1a the front portion A of the central body is divided into two halves by a longitudinal cleft H, the purpose of which is to divaricate during surgery the device already anchored through the rear arms F, so as to pass the two halves D from opposite sides with respect to the uterus and to be able to place the neck of the uterus more easily in the hole U.

- Figure 1b represents another front view of the device according to the invention, in which the dimensions, in particular those of the rear arms F and of the rear portion D, have been reduced to adapt the device to a smaller patient body size.

The present device may also be realised as in Figure 2a, with the longitudinal cleft H which cuts the rear portion D of the central body in two halves; this device
5 adapts to a type of surgical implant in which the front arms E are anchored first, then the rear part D is divaricated thanks to the cleft H so as to facilitate the entry of the neck of the uterus in the hole U, and lastly the rear arms F are anchored.

Figure 2b represents the same type of device with the cleft H in the rear portion D shown in Figure 2a, in which the dimensions of the device have been reduced to
10 adapt it to patients of a smaller size.

A further embodiment of the present device contemplates that the cleft H is present both in the front part and in the rear, thus cutting the device in two halves which are then rejoined at the time of surgery.

15 According to a further embodiment of the invention, the present invention has a central hole and a transverse cleft H which, starting from the central hole, cuts the central portion to the right of the hole, or the one to the left, in two halves.

Figure 3a represents the device according to the invention without the central hole U to be used, depending on the dimensions of the rear arms F described in
20 greater detail below, in cases of prolapse of the vaginal vault in patients without uterus, or in cases of partial prolapse.

Figure 3b represents the same type of device for patients of a smaller size.

With reference to Figures 1-3, the dimensions of the device according to the invention are for example the following:

- 25 - length a-a of the front arms E: between 8.0 and 15 cm; when the device is implanted by means of "tension free" operations, the length a-a is typically between 11 and 15 cm, and is preferably 13 cm; while for all the other types of surgical implant it is typically between 8.0 and 12.0 cm and is preferably 10 cm;
- length b-b of the front portion A: between 2.5 and 6.0 cm, and preferably 3.8 cm;
- 30 - length c-c of the front portion A: between 3.0 and 6.0 cm, and preferably 3.8 cm;
- width b-c of the front arms E: between 1.0 and 3.0 cm and preferably 2.0 cm;
- length d-y of the front portion A: between 2.5 and 6.5 cm, and preferably 4.0 cm;

- total length d-z of the device: between 11 and 15 cm, and preferably 12 cm;
 - distance y-x in the central hole U: between 0.6 and 1.6 cm, and preferably 1.1 cm;
 - distance x-e in the central hole U, the same as or different from the distance y-x:
5 between 0.6 and 1.6 cm, and preferably 1.1 cm;
 - length e-f of the rear portion D: between 1.8 and 4.0 cm, and preferably 2.3 cm;
 - width x-l: between 0.5 and 4.0, and preferably 2.5 cm;
 - distance h-h between the rear arms F: between 1.5 and 7.0 cm; for devices to be implanted in patients of a small size it is typically between 1.5 and 5.5 cm and is
10 preferably 3.5 cm, while for devices to be implanted in patients of a large size it is between 3.0 and 7.0 cm and is preferably 5.0 cm;
 - distance g-g between the rear arms F: between 4.9 and 10 cm; for devices to be implanted in patients of a small size it is typically between 4.9 and 8.9 cm and is preferably 6.0 cm, while for devices to be implanted in patients of a large size it is
15 between 6.0 and 10 cm and is preferably 7.6 cm;
 - distance i-i between the rear arms F: between 4.5 and 10.5 cm; for devices to be implanted in patients of a small size it is typically between 4.5 and 8.5 cm and is preferably 6.5 cm, while for devices to be implanted in patients of a large size it is between 6.5 and 10.5 cm and is preferably 8.0 cm;
 - 20 - length h-i of the rear arms F: between 2.5 and 6.5 cm, and preferably 4.5 cm.
- The dimensions of the device according to the invention without a hole illustrated in Figure 4, are the same as given above for the embodiments illustrated in Figures 1-3, except for the length h-i of the rear arms and therefore for the total length d-z of the device.
- 25 In facts, the device illustrated in Figure 4, depending on whether it is to be implanted in patients with partial prolapse or in patients without uterus with prolapse of the vaginal vault, may have rear arms of different lengths.
- A device suitable in the case of partial prolapse has for example the following dimensions:
- 30 - total length d-z of the device: between 4 and 8 cm, and preferably 5.1 cm;
 - length h-i of the rear arms F: between 0.5 and 3 cm, and preferably 1.1 cm;

while the device suitable in cases of prolapse of the vaginal vault has the following dimensions:

- total length d-z of the device: between 10 and 13 cm, and preferably 11 cm;
- length h-i of the rear arms F: between 2.5 and 6.5 cm, and preferably 4.5 cm.

5 The device according to the invention must be made of a material having a reticular or laminar structure, so as not to retain exudates and organic liquids which could build up on the central body of device, in particular in area A.

Any material having a reticular or laminar structure, whether it be of organic or synthetic origin, is suitable for the realisation of the present device as long as it
10 maintains its structure more or less unchanged over time and remains fixed in the position in which it was inserted during surgery.

Numerous synthetic materials are currently on the market which could be used to make the present device, for example materials based on single-filament polypropylene for use in surgical implants, in particular the reticular materials
15 composed of mixtures of polypropylene and polyglactin.

Materials of organic origin that could be used according to the invention are for example membrane of bovine pericardium, human fascia lata, acellular matrix of pig collagen, and submucosa of pig small intestine, suitably treated so as to be sterile and unable to transmit animal pathologies, and to remain more or less
20 unaltered over time.

Examples of commercial product of organic origin that could be used according to the invention are for example membrane of bovine pericardium treated with glutaraldehyde and heparin, produced by Shelhigh and marketed under the name Dome Pericardial Patch No-React[®] Treated, pig intestine submucosa produced by
25 DePuy OrthoTech and known by the trade name SIS (small intestine submucosa), or reticular porcine collagen marketed by Bard under the name Pelvicol[®].

The materials of organic origin are preferably used in the realisation of the present device as they are generally well tolerated by the organism, they do not give foreign body reactions, they are soft and impalpable and there is minimum risk of
30 erosion of the tissues with which they come in contact.

The dimensions of the holes in the materials that may be used according to the invention have a diameter preferably comprised between 0.01 cm and 0.05 cm

and more preferably 0.03 cm, at a distance from each other preferably of between 0.06 and 0.1, and more preferably 0.08.

The present device is applied by surgery; during surgery, the habitual means of access is the vagina, with an incision extending from the front vaginal wall to the rear wall, excluding the neck of the uterus.

Through the front vaginal wall the tendinous arch of the levator ani is penetrated, which is opened bilaterally for about 2 cm, and on which the two arms E are fixed respectively on the right and on the left.

The two rear arms F are then passed by the sides of the neck of the uterus, one on the right and one on the left, and are laid until the central part B surrounds the neck of the uterus. The right and the left half of the rear portion of the device are rejoined in the centre with two stitches and the rear arms are fixed bilaterally to the sacrospinous ligament or to the iliococcygeal muscle. At the end of the operation the device, anchored by means of the four arms to the tendinous arch of the levator ani and to the sacrospinous ligament (or to the iliococcygeal muscle), is at the normal anatomical level of the levator ani muscle. Consequently, also the organs resting on it, the bladder at the front (cystocele), the neck of the uterus in the centre (hysterocele, the rectum at the rear (enterocele), are returned to their correct anatomical plane above said muscle.

The operation can also be carried out by fixing first the two rear arms, using the device in which the cleft extends longitudinally from the central hole, cutting the front portion A.

Alternatively, the device according to the invention may be used which has the cleft H both in the front part and in the rear, and is therefore composed of two specular halves; in this case the operation is carried out by fixing first one half through the two front and rear arms and then the other half; the two halves already fixed both at the front and at the rear are then rejoined on the front portion A and on the rear portion D, taking care to position the neck of the uterus in the central hole U.

In the case of the device with a horizontal cleft, the procedures for passing around the neck of the uterus are the same as described above for the devices with a longitudinal cleft, and the suture of the cut of the device will be in a lateral position.

In patients without uterus, the operation may be carried out using the device represented in Figure 3, fixing first the front arms and then the rear arms, or vice versa.

Moreover, in patients suffering of a partial prolapse of pelvic organs, the operation
5 may be carried out by using the device illustrated in Figure 4; in this case the vaginal surgery procedure comprises making an incision extending from the front vaginal wall to the cervix; penetrating the tendinous arch of the levator ani through the front vaginal wall; bilaterally opening said tendinous arch for about 2 cm; fixing the two front arms of the said device respectively on the right and on the left
10 on the said opened tendinous arch; and bilaterally fixing the rear short arms to the neck of the uterus.

All the cases described above may also be realised by means of "tension free" operations, in which the present device is positioned inside the vaginal cavity without fixing it with stitches, but only making dissections in the tendinous arch of
15 the levator ani which guarantee the positioning of the front arms E. In this type of "tension free" operation the device according to the invention must have the opening of the front arms, represented in the figures by the length a-a, between 11 and 15 cm; moreover, it is preferable to use devices made of polypropylene and similar.

Moreover, as well as by the only vaginal approach, the operation may be carried
20 out with a mixed vaginal/abdominal or vaginal/laparoscopic approach, or by means of mini-invasive surgery.

The invention being as described, it is clear that this device may be modified in various ways; these modifications are not to be considered as divergences from
25 the spirit and from the prospects of the invention and all those modifications which would appear evident to an expert in the field are included within the scope of the following claims.